

**REMARKS**

Applicant requests reconsideration of the application in view of the following amendments and remarks.

**The claim amendments**

Claims 1-13 are pending. Applicant has amended claims 1, 4, 5, 9 and 12 either to improve their form or to overcome the Examiner's rejections.

First, applicant has amended claim 1 (1) to recite that the yeast cells are "of a *Saccharomyces* strain," (2) to recite the subject for treatment as "a subject having epilepsy," (3) to recite that the yeast cells are cultured under EMF "for a period of 50-380 hours" (support for this amendment is found at, e.g., page 14, lines 19-24 of the specification) , and (4) to indicate that the nature of the yeast cells that have been cultured in the presence of an EMF is compared with that of "yeast cells of the same *Saccharomyces* strain not having been so cultured." Applicant has similarly amended claim 9.

Second, applicant has amended claim 4 to delete yeast species that are not a *Saccharomyces* species.

Third, applicant has amended claim 5 to delete the yeast strain *Saccharomyces cerevisiae* Hansen AS 2.501.

— Finally, applicant has amended claim 12 to improve its form by reciting "treating epilepsy in a subject having epilepsy."

No new matter is introduced by the amendments. These amendments are further discussed below in the context of the Examiner's rejections.

**Rejection under 35 U.S.C. § 112, first paragraph: claim 5<sup>1</sup>**

The Examiner has rejected claim 5 for alleged lack of enablement.

The Examiner states that the yeast cells, as a required element of the claimed invention, must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. The Examiner alleges that the specification does not provide a repeatable process for obtaining the yeast cells and that it is not apparent that they are readily available to the public. The Examiner then proceeds to require deposit of the yeast cells in accordance with all the criteria set forth in 37 C.F.R. §§ 1.801-1.809. Applicant traverses.

The claimed yeast cells are obtained by treating publicly available parent yeast cells from China General Microbiological Culture Collection Center (“CGMCC”). There is clear information on the record indicating that all of the recited parent strains in amended claim 5 are publicly available. Exhibit A (enclosed herewith) indicates that CGMCC is a public depository whose main function is “to supply CGMCC cultures to scientists, industrial, agricultural and educational institutions.” Additionally, the address for CGMCC is provided at page 3, lines 3-7 of the specification. Further, all the parent yeast strains recited by their accession numbers in amended claim 5 are available from CGMCC: all these strains are listed on the CGMCC website.<sup>2</sup> See the attached printout of the webpage “*Saccharomyces*

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<sup>1</sup> Because this rejection seems to pertain to specific yeast cells/strains which the Examiner requests to be deposited, applicant presumes that the rejection is against claim 5, rather than claim 4.

<sup>2</sup> To expedite prosecution of the present application, applicant has amended claim 5 to delete yeast strain AS2.501, merely because it is not listed in the web printout, and not because it is not publicly available. Applicant hereby expressly reserve the right to pursue subject matter pertaining to AS2.501 in continuing applications claiming benefit from the present application.

“*Saccharomyces cerevisiae* Meyen ex Hansen Chinese Strain Name”

(<http://www.im.ac.cn/database/CCCCM/YEAST/y122.htm>), April 24, 1996

(hereinafter the “web printout”).<sup>3</sup> Thus, the parent yeast strains recited in amended claim 5 are not only known in the art, but are also readily available to the public.

Applicant has not deposited the claimed, activated yeast cells, which are derived from the parent yeast strains readily available from CGMCC. 37 C.F.R. §§ 1.801-1.809 do not require such deposit. 37 C.F.R. § 1.802(b) states that “[b]iological material need not be deposited . . . if it is known and readily available to the public or can be made or isolated without undue experimentation” (emphasis added). The specification provides ample guidance as to how to treat publicly available parent yeast cells, such as those obtainable from CGMCC, to arrive at the claimed composition. See, e.g., page 11, line 17 to page 18, line 25 of the specification. Thus, the claimed yeast cells of this invention need not be deposited.

For the above reasons, applicant requests that the Examiner withdraw this rejection.

**Rejection under 35 U.S.C. § 112, first paragraph: claims 1-13**

The Examiner has rejected claims 1-13 for allegedly lacking enablement. The Examiner states that the specification, while enabling for a yeast composition and method for its preparation and administration comprising EMF-treated *Saccharomyces cerevisia* for the treatment of epilepsy, does not enable such composition or method comprising EMF-treated yeast cells of all of the species recited in claim 4. Applicant traverses.

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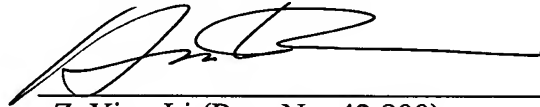
<sup>3</sup> This web printout has been cited by the USPTO as prior art dated April 24, 1996 in co-pending U.S. applications, e.g., in application No. 10/186,504.

However, to expedite prosecution, applicant has amended claims 1 and 9, and hence in effect also claims 2-8 and 10-13 (which depend from claims 1 or 9 either directly or indirectly), to recite "yeast cells of a *Saccharomyces* strain." Based on the guidance and examples provided in the application, it would not have required undue experimentation for one of ordinary skill in the art to practice the invention as claimed in *amended* claims 1-13. Accordingly, applicant requests that the Examiner withdraw this rejection.

**CONCLUSION**

Applicant respectfully submits that the application as amended is in condition for allowance, and early, favorable action is solicited.

Respectfully submitted,



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